MDR Eudamed
NBs & Certificates WG

Draft Planning - Roadmap

18/11/2016

Regulation milestones

Medical Devices

Entry into force	20 days after publication in the Official Journal	Art. 97 §1
Application	Three years after *Entry into force*	Art. 97 §2

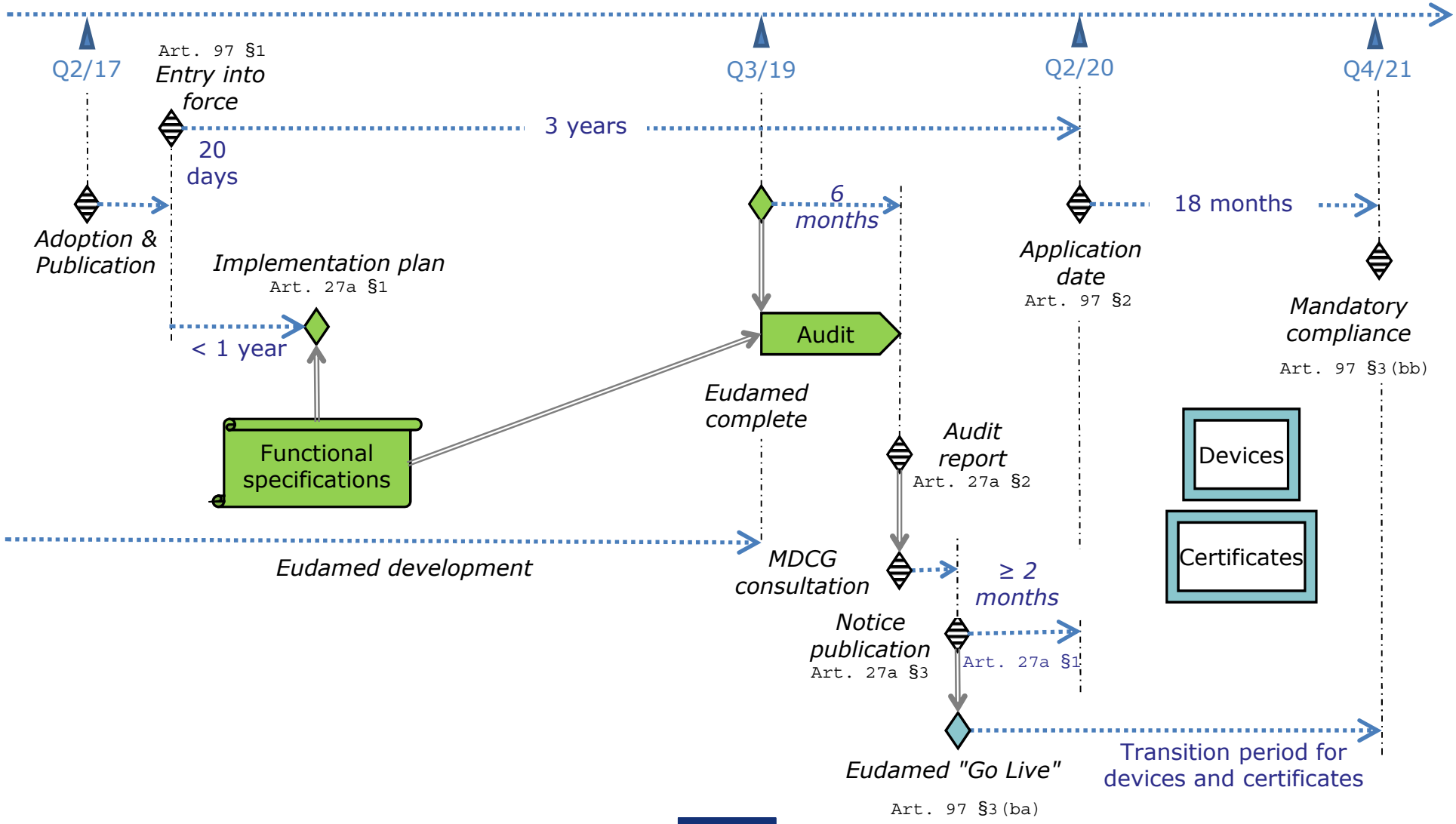
In Vitro Diagnostic Medical Devices

Entry into force	20 days after publication in the Official Journal	Art. 90 §1
Application	Five years after *Entry into force*	Art. 90 §2

Eudamed milestones

Functional specifications	EC to draw up in collaboration with the MDCG	MDR Art. 27a §1
Implementation plan of the *Functional specifications*	EC to draw up at the latest on *Entry into force* + 12 months	
Audit	Independent Auditors to verify compliance with *Functional specifications*	27a §2
Notice in the Official Journal	EC to publish after MDCG consultation at the latest two months before MDR *Application*	27a §1,3
"Go Live"	Eudamed may Go Live only after publication of the *Notice*	27a §1

Deadlines


Q2/17
Art. 97 §1
Entry into force
Q3/19
Q2/20
Q4/21
3 years
20 days
Adoption & Publication
Implementation plan
Art. 27a §1
< 1 year
6 months
18 months
Application date
Art. 97 §2
Mandatory compliance
Art. 97 §3(bb)
Audit
Functional specifications
Eudamed complete
Audit report
Art. 27a §2
Devices
Certificates
Eudamed development
MDCG consultation
≥ 2 months
Notice publication
Art. 27a §3
Art. 27a §1
Eudamed "Go Live"
Art. 97 §3(ba)
Transition period for devices and certificates

Supervising entity designation

MDR Art. 97 §3(b) states that Articles 28 to 40, 76 and 78 apply from *Entry into force* + 6 months

- **Member States appoint MDCG members** (Art. 78)
- **EC + Member States nominate experts to assess Notified Body designation requests** (Art. 32a)
- **Notified Bodies [may] request designation** (Art. 31)

(SRN and UDI not mandatory in Certificates issued before *Application*)

- ...

NB designation under MD Directives ceases at *Application* date (Art. 94 §1)

Mandatory compliance

Art. 97 §3(ba) states that three years after *Entry into force*, [using Eudamed] it shall be mandatory (i.a.) for:

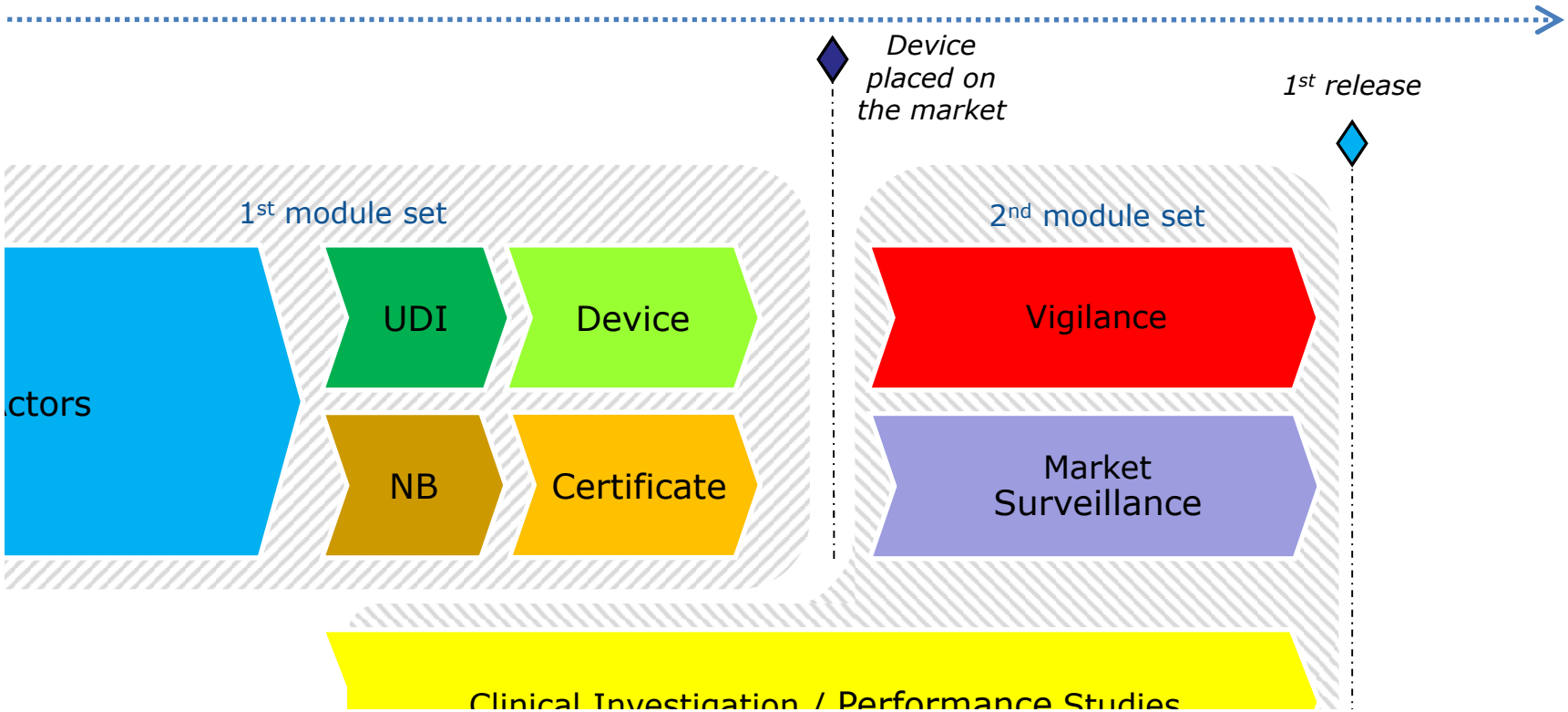
- **Manufacturers to obtain their *SRN***
- **Manufacturers to register the *Basic UDI-DI* of their devices**
- **Manufacturers to report their *Incidents***
- **Competent Authorities to manage their *Market Surveillance* data**
- **Sponsors to introduce *Clinical Investigation / Performance Studies***

Art. 97 §3(bb) states that 18 months after date of *Application*, before placing a device on the market, it shall be mandatory for:

- **Manufacturers to enter *device* data in Eudamed** (Art. 24b §3a)
- **Notified Bodies to enter *Certificate* data in Eudamed** (Art. 45 §4)

Business processes in Eudamed

e 27 MD/25 IVD - Electronic Systems included in Eudamed



Eudamed module sets

M: Identity & Access Management

- Authentication – Authorisation
- User Management

module set

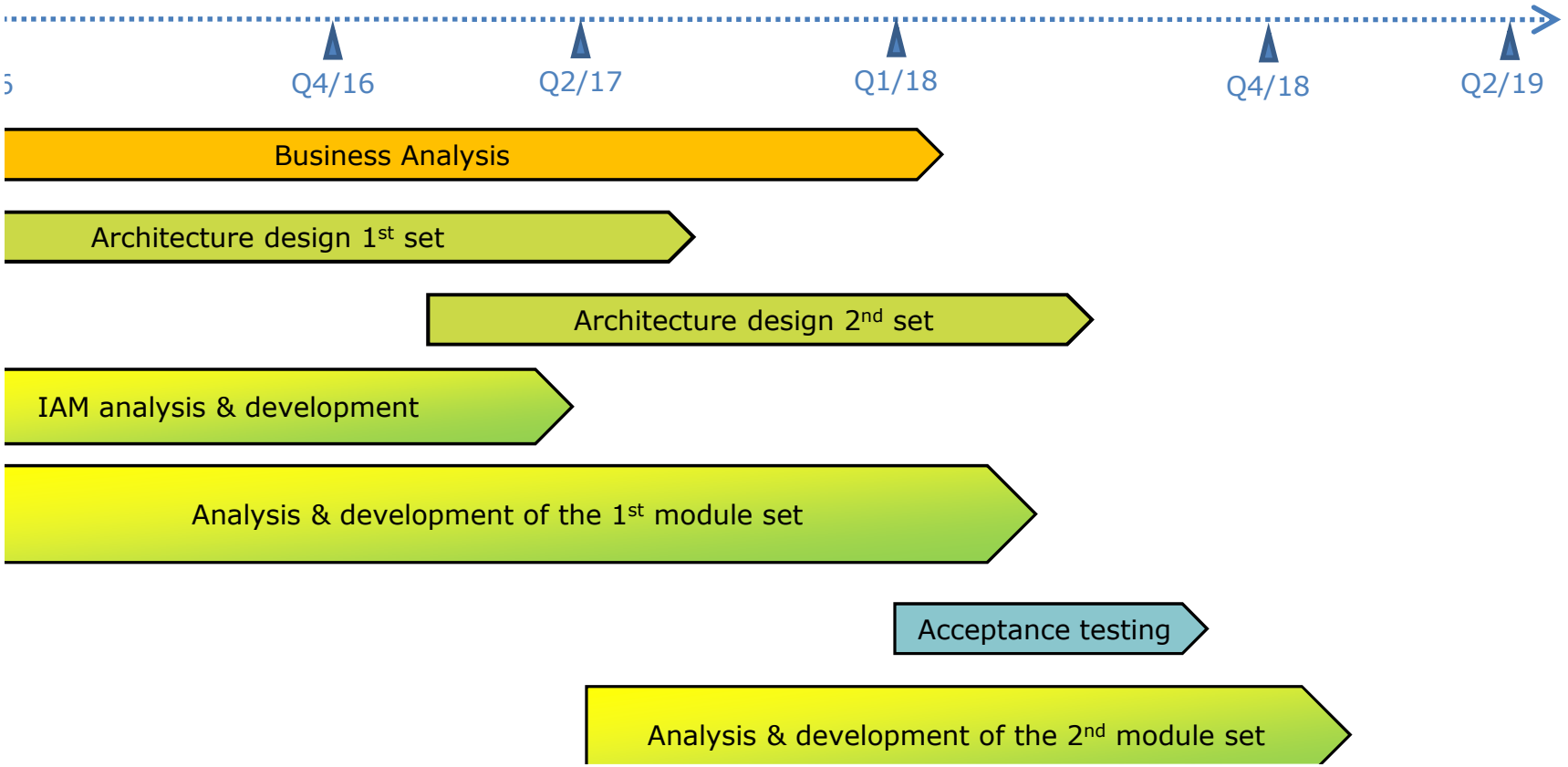
- Actor registration
- UDI
- Device
- Notified Bodies
- Certificates

module set

Ongoing consultation

participates in the Notified Bodies Operations oup (NBOG)

Global planning



NBs & Certificates

Business Analysis

Use Cases

Functional Requirements

Mock-up & prototyping

Mockup

Prototype

Technical Analysis & Design

Design model

Conclusion

ıing

mitment of resources for timely deliveries

ıress based on reviews of prototypes

ent

uirements based on consolidated text of Regulations

feedback should result in Business-friendly functionality

ess relies on your collaboration/involvement